



# UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/617,573  | 07/11/2003  | Jian Chen            | P1381R1C1P4C1       | 8245             |
| 9157  | 7590        | 08/14/2006           | EXAMINER            |                  |
| GENENTECH, INC.<br>1 DNA WAY<br>SOUTH SAN FRANCISCO, CA 94080 |             |                      | JIANG, DONG         |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1646                |                  |

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/617,573

Applicant(s)

CHEN ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 61-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/10/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED OFFICE ACTION**

Applicant's election of Group XIX invention, directed to SEQ ID NO:6, filed on 01 May 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendment filed on 01 May 2006 is acknowledged and entered. Following the amendment, the original claims 1-60 are canceled, and the new claims 61-83 are added.

Currently, claims 61-83 are pending and under consideration.

#### **Formal Matters:**

##### ***Information Disclosure Statement***

The information disclosure statement filed 10 October 2003 is acknowledged, and has been considered. A signed copy is attached hereto. Note, since the Blast results cited on the information disclosure statement (documents #26-29) are not true publications with a publication date, they are not fully in compliance with 37 CFR 1.97, and thus they will not be printed on the face of the patent issuing from this application.

##### ***Priority***

According to the priority statement of 7/11/03, it appears that priority is being claimed to a large number of utility and provisional applications. Most of these applications appear to be drawn to unrelated subject matter and are either not available for consideration or for which consideration to determine support for the instantly claimed subject matter would require an undue burden. Accordingly, the subject matter defined in claims 61-83 has an effective filing date of the US application 10/000,157, 10/30/01, as some pathological effect of the PRO10272 (IL-17E) on articular cartilage has been implicated, and the antagonist to IL-17E for the treatment of inflammation and cartilage defects such as arthritis has been suggested in the '157 application (Example 30, pages 137-139).

Art Unit: 1646

Applicants are requested to provide the serial number and specific page number(s) of any parent application to which priority is desired which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession and fully enabled of prior to 10/30/01.

### ***Title***

The title of the invention is not descriptive as the present invention is directed to a therapeutic use of an *antagonist* of an IL-17 homologous polypeptide. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

### ***Drawings***

The drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R. §§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures which consist only of nucleic acid or protein sequences (except those showing sequence alignment) which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO.'s), and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Appropriate correction is required.

### ***Specification***

The specification is objected to for the following informalities, appropriate correction is required for each item:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example, on page 26, line 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Art Unit: 1646

The use of the trademark has been noted in this application, page 128, lines 23 and 28 (“Taqman<sup>TM</sup>”), for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

**Rejections under 35 U.S.C. 112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61, 64-74 and 76-83 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 is indefinite for failing to adequately and specifically identify the structure of “a PRO10272 polypeptide”, from which the subject matter of the current invention was derived, as the claim does not recite any structural or functional limitation for the polypeptide. The claim merely defines the polypeptide with an arbitrary name, “PRO10272”, which is not a recognized name in the art, and thus, is not meaningful as to the structural identity of the molecule. As such, it is unclear what polypeptides are encompassed by this term. Since it is unclear what is meant by “a PRO10272 polypeptide”, the metes and bounds of the antagonist thereof cannot be determined either. Also, “a ... polypeptide” could be a fragment of the polypeptide, at any size. Therefore, the metes and bounds of the claim cannot be determined.

Claim 76 is indefinite for the recitation “at least *about* 85%” as neither the claim nor the specification defines the term. Therefore, it is unclear as to what range of sequence identity is covered by the term “about”, i.e., is 84%, 80% or 78%, for example, at least about 85%? The metes and bounds of the claim, therefore, cannot be determined.

The remaining claims are included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Art Unit: 1646

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the pharmaceutical composition comprising the antagonist of the PRO10272 polypeptide *and an immunosuppressant* (claim 73), wherein the immunosuppressant *is methotrexate* (claim 74).

**This is a new matter rejection.**

Claim 61, the dependent claims 62-74 and claim 75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method of treatment using an antagonist antibody to the PRO10272 polypeptide of SEQ ID NO:6, does not reasonably provide enablement for claims to a method of treatment using *an antagonist of a PRO10272 polypeptide* (claims 61-74), or a kit comprising a composition comprising *an antagonist* of the PRO10272 polypeptide of SEQ ID NO:6 (claim 75). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 61 is directed to a method of treatment using *an antagonist to a PRO10272 polypeptide*, wherein “*a PRO10272 polypeptide*” reads on any or all polypeptides possibly associated with a degenerative cartilaginous disorder as there is no structural or functional limitation for the polypeptide. As such, “*an antagonist*” thereto would read on any thing. Thus

Art Unit: 1646

the claims encompass a genus of molecules with broad structural diversity. However, the specification merely discloses one antagonist, the antibody to the PRO10272 polypeptide of SEQ ID NO:6, and the amino acid sequence of the murine ortholog of IL-17E (SEQ ID NO:41), and no other *PRO10272 polypeptide* or *antagonist* thereof meeting the limitation of the claim was ever identified or particularly described in the specification. Therefore, it is impossible to predict the structures of the antagonists encompassed by the claimed genus. Further, the specification fails to provide any guidance or working example as to how the skilled artisan could identify “a PRO10272 polypeptide” (based on structure, activity, both, or something else), and make the antagonists thereto in a manner commensurate in scope with the claim. With respect to claim 75, although it recites an antagonist of *the PRO10272 polypeptide of SEQ ID NO:6*, the issue remains because “an antagonist of” could be many things besides the antibody, such as a soluble receptors or the peptides with the same activity, antisense polynucleotides, or small chemical molecules, and the specification does not teach how to make those antagonists meeting the limitation of the claims. As one skilled in the art would not know how to make the encompassed antagonists in its full scope based on the instant disclosure, the artisan would not be able to practice the claimed method in a manner commensurate in scope with the claims, and it would require undue experimentation.

Due to the large quantity of experimentation necessary to identify additional PRO10272 polypeptides, to generate the infinite number of antagonists thereto as recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the unpredictable and complex nature of the invention, and the breadth of the claims which embraces a broad class of molecules with extreme structural diversity (“an antagonist”), and fails to recite any structural or functional limitation, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim 61, the dependent claims 62-74 and claim 75 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1646

Claim 61 is directed to a method of treatment using “*an antagonist of a PRO10272 polypeptide*”, claim 72 is directed to a pharmaceutical composition comprising the *antagonist* of claim 61, and claim 75 is directed to a kit comprising a composition comprising *an antagonist* of the PRO10272 polypeptide of SEQ ID NO:6.

However, with respect to “*a PRO10272 polypeptide*” in claim 61, the specification does not define the term, and merely discloses one PRO10272 polypeptide of SEQ ID NO:6, and the murine ortholog of IL-17E (SEQ ID NO:41). No other “PRO10272 polypeptide” was ever identified or particularly described in the specification. Further, the claim merely defines the polypeptide with an arbitrary name, “PRO10272”, which is not an art-recognized name. Such an arbitrary name gives no meaning as to the structural identity of “a PRO10272 polypeptide” as the claim recites no structural or functional limitation for the polypeptide. With respect to “*an antagonist*” in claims 61, 72 and 75, the term reads on a functional equivalent of any or all molecules having the “antagonizing” activity, and thus the claims encompass a genus of molecules with broad structural diversity, such as soluble receptors or the peptides with the same activity, antisense polynucleotides, or small chemical molecules, besides the antibodies. However, the specification merely discloses an antibody to the PRO10272 polypeptide of SEQ ID NO:6, and no other antagonist of said polypeptide meeting the limitation of the claim was ever identified or particularly described in the specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, with respect to “*a PRO10272 polypeptide*” in claim 61, none of the factors is present in the claim; and with respect to “*an (the) antagonist*” in claims 61, 72 and 75, the only factor present in the claims is a “functional” characteristic, i.e., an antagonist of a PRO10272 polypeptide, which structure is not defined. Therefore, with the exception of the PRO10272 polypeptide of SEQ ID NO:6 and the antibody thereto, the skilled artisan cannot envision the sequence structure of the encompassed PRO10272 polypeptides or the antagonists thereto. Accordingly, in the absence of sufficient



Art Unit: 1646

recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the instant application, applicants have one PRO10272 polypeptide (SEQ ID NO:6) and a murine ortholog (SEQ ID NO:41), and one type of antagonist thereto, the antibody. Therefore, only the antagonist antibody to the PRO10272 polypeptide SEQ ID NO:6 or 41, but not the full breadth of the claims (“an antagonist of a PRO10272 polypeptide”) meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### **Rejections Over Prior Art:**

The following rejections under 35 U.S.C. § 102 and 103 are made in view of the determination that the effective filing date for the instantly claimed invention is 10/30/01, which is the filing date of a prior application 10/000,157, and relied upon in the instant application for an earlier filing date under 35 U.S.C. 120.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1646

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 72 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al., US6,562,578.

Gorman discloses a polypeptide of human IL-17-like cytokine, IL-174, which has an amino acid sequence of SEQ ID NO:14. Gorman's polypeptide of SEQ ID NO:14 comprises amino acid residues 19-177 of the present SEQ ID NO:6 (177 amino acids) with 100% sequence identity (see computer printout of the search results). Additionally, the reference teaches antibodies to said polypeptide, and a reagent or composition thereof for *therapeutic use* (antibodies to the protein *as antagonists*), which comprises said antibody and conventional pharmaceutically acceptable carriers or diluents (column 44, lines 30-40, and 52-58, and column 45, lines 2-4), indicating a pharmaceutical composition. Gorman's antibodies to IL-174 would most definitely bind to the present PRO10272 polypeptide of SEQ ID NO:6 with the specificity because Gorman's polypeptide of SEQ ID NO:14 comprises about 90% of the present SEQ ID NO:6 with 100% sequence identity. Further, Gorman teaches that the quantities of reagents necessary for effective therapy will depend upon many different factors including means of administration, target site, physiological state of the patient, and other medicants administered, and thus, treatment dosages should be titrated to optimal safety and efficacy using in vitro and animal testing (column 45, lines 6-15), and that dosage ranges would ordinarily be expected to be in amounts lower than 1mM concentrations, ..., with an appropriate carrier (column 45, lines 26-31). Although Gorman is silent about the use of said antibody composition in treating a degenerative cartilaginous disorder (as that in the present claim 72), such is merely an intended use of the claimed composition, and does not alter the nature of the composition. Accordingly, Gorman's antibody composition anticipates claim 72. Furthermore, with respect to claim 75, Gorman teaches a kit comprising a binding compound (an antibody) binding to SEQ ID NO:14, a compartment, and instructions for use (claim 6, and column 4, lines 52-57), wherein the binding compound can be in a sterile composition (column 4, the last line to column 5, line 2). Although

Art Unit: 1646

Gorman does not explicitly mention that the instruction indicates said binding composition can be used for the treatment of a degenerative cartilaginous disorder (as the present claim), the new printed matter (instruction/label) to a known product do not make the product patentable even if the instruction details a new use for the product (*In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)). Therefore, the reference also anticipates claim 75.

**Conclusion:**

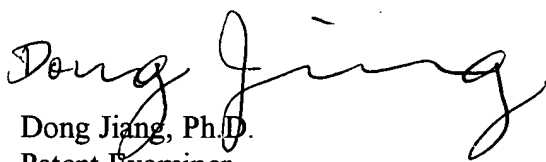
No claim is allowed.

Art Unit: 1646

**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in cursive script that reads "Dong Jiang".

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
7/18/06